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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,044	11/17/2003	Richard M. Chesbrough	71202-0048	4171

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/707,044	CHESBROUGH ET AL.	
	Examiner	Art Unit	
	Parikha S. Mehta	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42 and 44-71* is/are pending in the application.

4a) Of the above claim(s) *15, 20-22, 25, 28, 29, 38, 59-61, 64, 65 and 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-19,23,24,26,27,30-37,39-42,44-58,62,63,66,67 and 69-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/26/2007
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Newly submitted Figure 4D is sufficient to overcome the previous objection to the drawings. Accordingly, the previous objection to the drawings is hereby withdrawn.

2. Applicant's amendments to the specification are sufficient to overcome the previous objection to the specification for minor informalities. Accordingly, the previous objection to the specification is hereby withdrawn.

3. Applicant's amendments to claims 4, 16 and 27 are sufficient to overcome the previous objection to these claims for minor informalities. Accordingly, the previous objections to claims 4, 16 and 27 are hereby withdrawn. The previous objection to claim 23 is also withdrawn in view of Applicant's arguments.

4. Applicant's amendments to claims 42 and 45 are sufficient to overcome the previous rejection of these claims under 35 U.S.C. 112. Accordingly, the rejections of claims 42 and 45 under 35 U.S.C. 112 are hereby withdrawn.

Response to Arguments

5. Applicant's arguments filed 29 May 2007 have been fully considered but they are not persuasive.

Applicant argues that Foerster (US PG Pubs. No. 2005/0165305) fails to disclose a guide element connected to an imaging element, where the guide element extends exteriorly of the tissue mass when the imaging element is placed (Remarks p. 20, ¶ 1). Conversely, the pending claims recite "when the imaging element is placed within the tissue mass...at least part of the guide element extends exteriorly...when the separable portion is separated fromteh guide element, no part of the guide element extends exteriorly". As discussed in the prior Office Action, the connector 18a (Fig. 9) of Foerster ('305) constitutes the claimed guide element. As shown in reference Fig. 10, when the imaging element is placed in the tissue mass, at least part of the connector extends exteriorly beyond the tissue mass, as claimed. Furthermore, as illustrated in Fig. 11, when the connector is separated, no part of the element extends beyond the tissue mass, as claimed. Accordingly, Foerster ('305) does indeed disclose a guide element as claimed.

Applicant additionally contends that Foerster ('305) fails to disclose a holder mounted to a portion of a guide element, and that the claimed holder is not equivalent to a cannula (Remarks p. 20, ¶ 3). Examiner respectfully directs Applicant's attention to the definition of the words "holder" and "hold" as set forth by Merriam Webster (http://www.m-w.com):

***holder**: a device that holds*

***hold**: to enclose and keep in a container or within bounds*

In view of the fact that the connector of Foerster ('305) is enclosed and kept within the cannula (Figs. 9-11), it can, in fact, be said that the cannula constitutes a holder as claimed. As for the claimed limitation regarding the holder being mounted to a portion of the guide element, Examiner respectfully draws Applicant's attention to the definition of the word "mount" as set forth by Merriam Webster (http://www.m-w.com):

***mount**: to arrange or assemble for use or display*

Since the cannula is arranged in relation to the connector in such a way that facilitates use of the connector (in that it provides a path which enables the connector to traverse the patient's body), it can reasonably be concluded that the cannula is mounted to the connector (i.e., the "guide element").

Applicant further argues that Foerster ('305) fails to provide a threaded coupling as claimed (Remarks p. 21, ¶ 2). Specifically, Applicant alleges that the reference coupling mechanism "is not equivalent to a threaded coupling, **as Applicants have applied the term**" (emphasis added). It is noted that the specific features upon which applicant appears to be relying (i.e., the threaded coupling being a male/female screw mechanism as shown in Fig. 4D and described in ¶ [0048] of the specification) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, since the connector (guide element) is coupled to the imaging element by being threaded through the loop of the imaging, the reference invention does include a threaded coupling. Similarly, in response to Applicant's allegation that the reference connector is not unthreaded when removed (Remarks p. 22 ¶ 3), since the connector of Foerster ('305) is removed from the loop of the imaging element after placement of the imaging element, it can be said that the connector is "unthreaded" from the imaging element as claimed. For additional evidence to support Examiner's assertions regarding the claimed threaded mechanism, Examiner respectfully draws Applicant's attention to the definition of the word "thread" as set forth by Merriam Webster (http://www.m-w.com):

***thread**: 1 a: to pass a thread through the eye of (a needle) b: to arrange a thread, yarn, or lead-in piece in working position for use in (a machine)2 a (1): to pass something*

through in the manner of a thread <thread *a pipe with wire*> *(2): to pass (as a tape, line, or film) into or through something* <threaded *a fresh roll of film into the camera*>

Applicant argues that Foerster ('305) does not disclose an imaging element that can be repositioned. There is no disclosure in the Foerster ('305) reference that suggests that the imaging element could not be repositioned within the tissue mass. In fact, it would be quite possible for one of reasonable skill in the art to reposition the imaging element within the lesion via a surgical procedure, which is not excluded by the current claim language. Therefore, the imaging element of Foerster ('305) is releasable as claimed.

Applicant contends that Foerster ('305) does not disclose locating an area of interest in a tissue mass by following a guide element to an imaging element (Remarks p. 22 ¶ 4). As discussed in the previous Office Action, Applicant fails to provide, either in the claims or the supporting disclosure, a detailed explanation of exactly what is meant by "following a guide element." The mere recitation "the shaft extends... to be followed by the surgeon in locating the lesion" (Specification ¶ 0008) does not set forth specific steps for "following," nor do the claims provide any other additional detail. Accordingly, Examiner interprets the meaning of the term "to follow," as claimed, to encompass that which is set forth by Merriam Webster (http://ww.m-w.com), namely that it can mean any of "to watch steadily," "to keep the mind on," "to attend closely," or "to keep abreast of". One of ordinary skill in the art could reasonably conclude that the Foerster ('305) reference enables a surgeon to keep abreast of the position of the connector (and, hence, the imaging element, since it is disclosed to be disposed at the distal end of the guide element) during the procedure, and, therefore, one would be "following" the guide element to the imaging element as claimed.

Applicant argues that Foerster ('305) does not disclose a delivery apparatus that includes a piston (Remarks p. 23 ¶ 3). As recited in claim 70 and paragraph 41 of the specification, and as shown in Fig. 2 of the instant application, Applicant claims that the piston comprises a stylet. As previously discussed, the delivery apparatus of Foerster ('305) includes a stylet and therefore it can be said that the reference invention includes a piston as claimed.

For at least the reasons set forth above, Applicants arguments and amendments are ineffective to overcome the Foerster ('305) reference. All pending claims remain rejected in view of Foerster ('305) as set forth in the previous Office Action, the arguments of which are reiterated herein.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-14, 16-19, 23, 24, 26, 27, 30-37, 39-42, 44-58, 62, 63, 66, 67 and 69-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Foerster et al (US PG Pubs. No. 2005/0165305), hereinafter Foerster ('305), previously made of record.

Regarding claims 1-4, 30-33, 35-37, 40, 46, 47, Foerster ('305) discloses means and steps for localizing a tissue mass via a device comprising a marker and a connector separably connected to the marker, wherein the connector may be unthreaded from the marker by pulling the connector (Figs. 9-11). The marker and connector of Foerster ('305) constitute an imaging element and a guide element, respectively, as claimed in the instant application. Foerster ('305) shows that, when the marker is placed within the tissue mass, the connector extends exteriorly of the tissue mass, and when the connector is separated from the marker, no part of the connector extends from the tissue mass (Figs. 10 & 11). Foerster ('305) states that the marker may be visualized via any state of the art imaging system (Abstract).

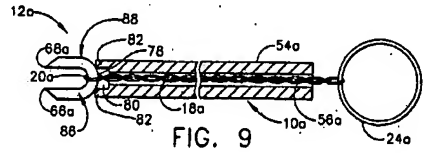


FIG. 9

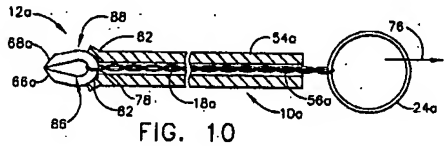


FIG. 10

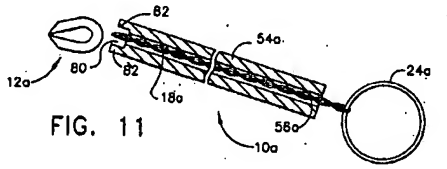


FIG. 11

Source: Foerster et al (US PG Pubs. No. 2005/0165305)

Regarding claims 5-8 and 48-50, Foerster ('305) states that the marker may be made of titanium or other biodegradable material (¶ 0023, 0024, 0077).

Regarding claims 9-13 and 51-54, Foerster ('305) shows that the marker may include at least one extension, and further shows that the marker may comprise a loop through which the connector passes (Figs. 13, 14, 18).

Regarding claims 14, 26, 55 and 62, Foerster ('305) shows that the connector is a filament (Figs. 9-11).

Regarding claims 16, 27 and 63, Foerster ('305) discloses that the connector comprises a wire (¶ 0020).

Regarding claims 17 and 56, Foerster ('305) states that the marker and connector are delivered to the biopsy site via a cannula, equivalent to the holder claimed in the instant application (¶ 0017).

Regarding claim 18 and 57, Foerster ('305) discloses that the connector includes a failure point, at which the element may be separated from the marker after the marker has been placed in the tissue (¶ 0020 & 0049, Fig. 11).

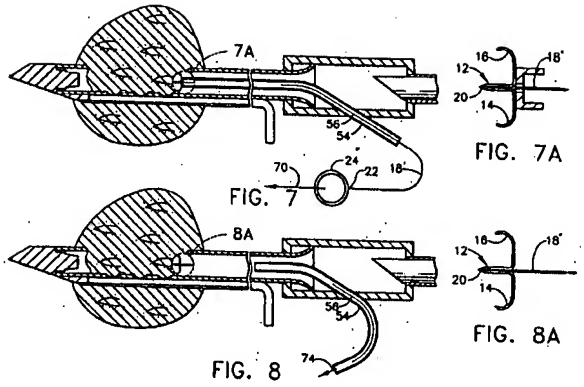
Regarding claims 19 and 58, the connector of Foerster ('305) is coupled to the marker by being threaded through the loop of the marker (Fig. 10).

Regarding claims 23 and 66, Foerster ('305) provides a pull ring attachable to the guide element (Figs. 9-11, element 24a). The pull ring of Foerster ('305) is equivalent to a gripping element as claimed in the instant application.

Regarding claim 24, the marker of Foerster ('305) is capable of being releasable and repositioned, for example by surgery.

Regarding claims 3, 39 and 41, the breaking of the connector loop as shown by Foerster ('305) constitutes a cutting mechanism as claimed in the instant application (Figs. 9-11). Foerster ('305) also states that the connector is discarded after it is detached from the marker, which constitutes removing the cut portion of the guide element as claimed in the instant application (¶ 0049).

Regarding claims 44 and 45, Foerster ('305) states that entire biopsy instrument may be mounted on a commercially available stereotactic guidance system (¶ 0043). The delivery assembly components of Foerster ('305) comprise a self-contained marking apparatus as claimed in the instant application (Figs. 7-8A).



Source: Foerster et al (US PG Pubs. No. 2005/0165305)

Regarding claim 67, Foerster ('305) states that the delivery assembly is repositionable after release of the marker (¶ 0059).

Regarding claims 69 and 70, Foerster ('305) provides cannula having a distal opening and a spring, which is slidably disposed within the lumen of the introducer, wherein the spaced is spaced inwardly from the expulsion opening prior to release of the marker into the tissue mass (¶ 0057-0060). The spring of Foerster ('305) constitutes the stylet claimed in the instant application. Foerster ('305) also provides an imaging element and guide element as previously discussed for claim 1. When the spring of Foerster ('305) is advanced within the cannula, the marker is released into the tissue mass as claimed in the instant application (¶ 0059).

Regarding claim 71, Foerster ('305) states that a portion of the marker may be made of non-bioabsorbable material (¶ 0024).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha S. Mehta whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Parikha S. Mehta
Examiner – Art Unit 3737

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